Remarks

Double Patenting Rejections

Claims 36-40 and 48-49 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 19, 20, and 21 of U.S. Patent No. 5,403,317. Furthermore, claims 36, 37, 39, 40 and 48 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,694,951. In response and in order to expedite the prosecution of this application, Applicant submits herewith Terminal Disclaimers to obviate these double patenting rejections. It should be understood that these Terminal Disclaimers are being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimers are necessary.

In addition, claim 1 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatenable over claim 1 of U.S. Patent No. 5,269,785. In response, Applicant has canceled claim 1.

35 U.S.C. §102 Rejection

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,857,045 to Rydell. As previously noted, Applicant has canceled claim 1.

Claims 36-39, 42-47, 49-55, 57-59, 69, 70, 73 and 74 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,226,877 to Epstein ("Epstein"). For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Epstein.

Epstein teaches a method for preparing fibrinogen adhesive in which the process begins with the withdrawal of whole blood from an autologous, or other, or multiple donors in the presence of an anticoagulant, and separation of plasma from the red blood cell fraction. (col. 6, lines 1-4). After the plasma is separated from the red blood cells, it is treated directly, at ambient temperature, without prior treatment to remove thrombin, with a physiologically acceptable non-toxic precipitant. (col. 6, lines 16-20). The concentrated solution or, in some instance, undiluted

precipitant is added to the plasma in an amount effective to precipitate the fibrinogen adhesive composition of the invention. (col. 6, lines 37-40). The precipitate containing the fibrinogen adhesive is then recovered, typically by centrifugation. (col. 6, lines 54-55). Commercial preparations of thrombin and calcium ion may be added with the fibrinogen adhesive. (col. 10, lines 48-50). In a particularly advantageous way to apply the two components of the sealant to the tissue to be cemented, a dual-barreled applicator with one barrel for supply of the fibrinogen adhesive and the other for the thrombin/calcium ion mixture is employed. (col. 10, lines 53-57).

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. Removed tissue may be centrifuged if necessary or desired, keeping the components such as bone, cells, and blood and discarding fluid. The surgeon can place other substances into the graft material to be implanted, such as other tissue graft material, collagen, antibiotics, or ceramic hydroxyapatite or tricalcium phosphate to aid in bone ingrowth. Before implantation, harvested tissue fragments are preferably packed or compressed into a plug of tissue graft material. Alternatively, the tissue fragments may be left in a more loose state, or only certain selected cells, components, or tissue fragments are used. Any suitable means of packing or compressing fragments may be used.

Therefore, to further highlight these distinctions of the present invention, Applicant has amended independent claims 36 and 69 to be in a form analogous to claim 48, against which no prior art was cited. Claim 48 has been canceled. Independent claim 50 has also been canceled and claim 53 has been rewritten in independent form to include all the elements of canceled claim 50. Claim 53 also now further specifies that a bone growth promoter is added to the body tissue prior to implantation. Epstein does not teach or suggest at least this feature since Epstein is directed to a method of making an adhesive from blood components.

Based on the foregoing, Applicant respectfully submits that independent claims 36, 53, and 69 are now in condition for allowance. Based at least on their dependency, Applicant also respectfully submits that dependant claims 37-39, 42-47, 49, 51, 52, 54-55, 57-59, 70, and 73-74 are allowable as well.

35 U.S.C. §103 Rejection

Claims 61-69 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,678,470 to Nashef *et al.* ("Nashef") in view of Epstein. Specifically, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use blood derived adhesive of Epstein to adhere the bone grafting material of Nashef into the implantation site. For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Nashef and Epstein, either alone or in combination.

Nashef discloses a biologically derived, biocompatible, non-antigenic, and incorporatable material for use as a generic bone substitute, as well as the process for making this material. The bone substitute material is derived from glutaraldehyde-tanned bone. (col. 1, lines 56-60).

In contrast, the present invention teaches a surgical procedure for harvesting tissue. One or more selected components can be separated from the harvested tissue fragments. (col. 4, lines 21-22). The selected components may include bone, cells, and blood. (col. 9, lines 1-2). The harvested tissue and/or the selected components are then implanted into the body of a patient. (col. 4, lines 23-24). As previously noted, a number of substances can be added to the implanted tissue. However, none of the substances identified in the specification are tanning agents or have the effect of a tanning agent.

Applicant has amended claim 61 to include tissue free from tanning substances. Applicant respectfully submits that independent claim 61 is now in condition for allowance. Based at least on their dependency, Applicant submits that claims 62-68 should be allowable as well. In regard to independent claim 69, Applicant respectfully submits that the §103 rejection should be withdrawn. Applicant contends that the amendment made to this claim with respect to the §102 rejection is applicable here as well.

Subject Matter Indicated as Being Allowable

Applicant acknowledges with appreciation that claims 41, 56, 71, 72, 75, and 76 were indicated as being allowable if rewritten in independent form. In response, Applicant has rewritten claims 41, 56, and 71 in independent form. Claim 72 has been rewritten to depend from claim 71

and claims 75 and 76 remain dependent from claim 69, which is believed to be in condition for allowance.

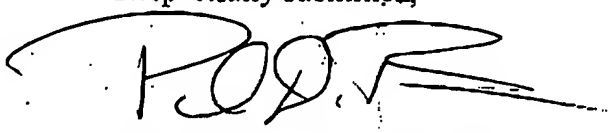
Applicant notes that no prior art was cited against claims 40 and 60. In order to expedite prosecution of this case, Applicant has amended claims 40 and 60 to be in independent form. In amending these claims to be in independent form, Applicant has included all the elements of the base claim. Accordingly, Applicant respectfully submits that claims 40 and 60 are now in condition for allowance.

Conclusion

In light of the foregoing, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $278.00 is believed to be due for two terminal disclaimers plus four additional independent claims (at small entity rate) is believed to be due with this submission and a Fee Transmittal Sheet including this fee is submitted concurrently herewith. Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-014-8).

Respectfully submitted,



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